K043322

510(k) Summary
(As Required by 21 C.F.R. §807.92)

JUL 2 1 2005

Submitted by:	Hager Worldwide, Inc. 13322 Byrd Drive Odessa, FL 33556
Date of summary:	This summary was prepared on June 30, 2005.
Device name:	Hager MIRAMATIC Safety Syringe System
Common name:	Dental cartridge syringe system with antistick feature, needle re-capper, and sharps container.

Classification names:

Regulation Number and ProCode	Classification Name
872.6770, EJI	Cartridge Syringe
872.4730, DZM	Dental Needle

Predicate Devices	SafeStep™ Safety Dental Cartridge Injector K022959 ("1-Shot™ Safety Syringe."). Dental needles are 510(k) exempt.
Modifications	The device employs a compression fit loading and ejecting needle hub rather than threaded connection.
Intended Use	Indicated for use with pre-filled anesthetic cartridges and press fit dental needles for the manual injection of local dental anesthetics into the oral tissues. The cartridge syringe may aid in the reduction of needle stick injuries.
Technological Characteristics	The Hagar MIRAMATIC System consists of a cartridge syringe (the MIRAMATIC) and dental needles (MIRAJECT). The MIRAMATIC System is a manual system designed exclusively for use with MIRAJECT needles. The hub of the syringe is designed to receive the needle using a compression fit mechanism rather than a threaded screw-on motion or slip-fit. The needles have a corresponding specially designed cone to allow seating by push fit on to the hub. The syringe hub has locked and unlocked positions.
Testing	Testing activities were conducted to establish the performance and reliability characteristics of the new device with respect to the predicates. Testing involved mechanical testing, cleaning and sterilization efficacy and simulated clinical evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2005

Hager Worldwide, Incorporated
c/o Mr. James Delaney
4 Lincoln Street
Andover, Massachusetts 01810

Re: K043322
Trade/Device Name: Miramatic Safe Syringe System
Regulation Number: 21 CFR 872.6770
Regulation Name: Cartridge syringe
Regulatory Class: II
Product Code: EJI
Dated: July 1, 2005
Received: July 5, 2005

Dear Mr. Delaney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043322

Indications for Use

510(k) Number (if known): K043322

Device Name: Hagar MIRAMATIC Safe Syringe System

Indications for Use:

Indicated for use with pre-filled anesthetic cartridges and press fit dental needles for the manual injection of local dental anesthetics into the oral tissues.

The cartridge syringe may aid in the reduction of needle stick injuries.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K043322

(Posted November 13, 2003)